

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in Exhibit A
attached hereto

ORDER ADOPTING
MEMORANDUM OPINION AND ORDER
(*Daubert* ruling re: Vladimir Iakovlev, M.D.)

On August 14, 2017, the defendants filed a Notice of Adoption of Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Vladimir Iakovlev Filed in Wave 5. [ECF No. 4312]. The court **ORDERS** that the Memorandum Opinion and Order (*Daubert* Motion re: Vladimir Iakovlev, M.D.) [ECF No. 2710] ("Prior Order") entered on September 1, 2016, as to the Ethicon Wave 1 cases is **ADOPTED** in the Wave 5 cases as identified in Exhibit A.¹ The Prior Order is attached hereto as Exhibit B.


Importantly, the court notes that the expert opinions proffered in Wave 1 are in almost every respect identical to those proffered here. The court has found, however, that with each entered Order, the experts in these cases attempt to bolster or fine-tune the support for their opinions, but the opinions themselves do not change. Accordingly, the court will refrain from engaging in the extremely inefficient practice of continuously reexamining the qualifications, reliability, and relevance of dozens of experts and their

¹ On Exhibit A, I have marked through cases that are closed, on the inactive docket, not in Wave 5, could not be identified because of an error in the style or case number, or assigned to another District Judge.

numerous opinions. While the parties continue to challenge even the slightest alteration to the underlying support for an expert's opinion, the court's review of the parties' arguments reveals that these refreshed *Daubert* challenges are different from previous arguments by only the very slightest of degrees. The court **FINDS** that to the extent that the parties raise arguments not previously addressed by the court's Prior Order, the trial judge may easily resolve these issues at trial without the need for further briefing or an evidentiary hearing. Accordingly, the court **ORDERS** that to the extent that the parties raise *Daubert* challenges not previously addressed in the court's Prior Order—fully adopted herein—those challenges are **RESERVED for trial**.

The court **DIRECTS** the Clerk to file a copy of this Order Adopting Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 5 cases identified in the Exhibit attached hereto.

ENTER: July 27, 2018



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

Case Name	Docket Number
Abadie, Mary J.	2:12cv07356
Appleton, Rita M. & Charles E.	2:12ev07872
Avant, Debbie & Jack	2:12ev07413
Ball, Sammie Marie	2:12cv07415
Balura, Cathy & Peter	2:12cv07854
Bell, Tammy Louise & Shandon	2:12ev06474
Bethune, Susan & Ronnie Jerome	2:12ev07852
Bohne, Chantel	2:12ev07417
Bordelon, Jane & Frederick, III	2:12cv07431
Clowe, Paula Carole	2:12ev06893
Clowes, JoAnn	2:12ev05749
Dawes, Glenda & Marvin, Sr.	2:12ev08048
Dobard, Raja	2:12ev07493
DuBois, Virginia L. & Ronald	2:12cv08070
Dupont, Catherine & Richard	2:12ev07490
Dynes, Donna & Bobby	2:12ev06104
Foy, Connie & Charles	2:12ev06589
Frame, Patsy	2:12ev07524
Fremin, Margaret Richard	2:12ev07523
Gregersen, Gina Lynn	2:12ev06299
Harris, Sabrina	2:12ev07582
Hawks, Christie S.	2:12ev07257
Heintz, Kathleen	2:12ev07579
Hosbrook, Patricia	2:12cv07843
Jacob, Liberty & Jack	2:12ev06954
Jarrell, Kimberly & Stevie Lee	2:12ev07422
Jaufre, Dianne	2:12ev07573
Jones, Leslie & Calvin	2:12ev07476
Kaviratna, Hema & Padma	2:12ev08019
Landecche, Mary Alice & Nolan, Jr.	2:12ev07962
Lee, Amy	2:12ev07478
Leith, Sherrie	2:12cv08079
Lockwood, Maria	2:12ev07649
Martin, Linda A. & Henry	2:12ev07853
McCoy, Clarisa	2:12ev07646
McCumber, Betty Linton	2:12cv08083
McLain, Jamie & Travis	2:12ev08004
Miller, Joycelyn	2:12ev07644
Murray, Sharon & Robert	2:12ev07705
Patterson, Elizabeth	2:12ev06081
Platt, Mary Lee & Clair	2:12ev07420
Rayburn, Judy & Brian E.	2:12ev07711
Reyes, Monnica & Marces	2:12ev06141
Ross, Veronica A.	2:12ev07419
Sampson, Beverly	2:12ev07424
Santana, Santa	2:12cv07849
Sciumbata, Teresa & Giuseppe	2:12cv07037
Scott, Cassandra	2:12cv07846
Shary, Maureen & Dennis M.	2:12ev07483

Case Name	Docket Number
Sutherlin, Anita	2:12cv07479
Taylor, Bessie & William, Sr.	2:12cv07784
Terrebonne, Shirley	2:12cv07779
Thompson, Lissa	2:12cv06140
Thorson, Rachel & James	2:12cv07481
Tichbourn, Loral	2:12cv07777
Underwood, Martha A.	2:12cv06162
Valverde, Jodi & Leffy	2:12cv07999
Vazquez, Yadira & Ricardo	2:12cv07840
Washburn, Suzanne	2:12cv06248
Weaver, Karen & Victor E.	2:12cv07769
Wells, Stephanie & Larry	2:12cv06438
Wilcher, Patricia	2:12cv06573
Wright, Debbie	2:12cv07676

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Vladimir Iakovlev, M.D.)

Pending before the court is the Motion to Exclude the Opinions and Testimony of Dr. Vladirmir¹ Iakovlev [ECF No. 2066] filed by Johnson & Johnson and Ethicon, Inc. (collectively “Ethicon”). The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse (“POP”) and stress urinary incontinence (“SUI”). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL.

In this MDL, the court’s tasks include “resolv[ing] pretrial issues in a timely

¹ The proper spelling of Dr. Iakovlev’s first name is Vladimir.

and expeditious manner” and “resolv[ing] important evidentiary disputes.” Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order (“PTO”) No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.²

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties’ misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony

² Ethicon identified the Wave 1 cases affected by this Motion in its attached Exhibit A [ECF No. 2066-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my

interest in accuracy counsels reserving ruling until the reliability of the expert testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of “junk science” looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court’s prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—I will therefore reserve ruling until expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal

Rules of Evidence and *Daubert*, so the court will not linger for long on these standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her “knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

- (1) whether a theory or technique can be or has been tested;
- (2) whether it has been subjected to peer review and publication;
- (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
- (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts “principles and methodology” above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g., Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Vladimir Iakovlev is a clinical pathologist at St. Michael’s Hospital in

Toronto, Canada. Each year, he conducts approximately 5,000 pathological examinations in his practice.

a. Properties

i. Degradation

Ethicon seeks exclusion of Dr. Iakovlev's degradation opinions, which it claims are unreliable. As an initial matter, Ethicon seeks to exclude *all* of Dr. Iakovlev's degradation-related testimony when in fact, Ethicon disputes the reliability of a specific opinion about degradation bark. Ethicon argues that the "central theory underlying all of Dr. Iakovlev's degradation opinions is that the Prolene in Ethicon mesh products degrades *in vivo* creating cracks in the degraded Prolene that trap histological stains, which Dr. Iakovlev can detect via light microscopy." Mem. 4 [ECF No. 2070]. A review of Dr. Iakovlev's report shows this is a mischaracterization of his proposed testimony. Dr. Iakovlev's testimony on degradation generally is extensively supported with specific references to the scientific literature and several internal Ethicon documents. His manner of corroborating the scientific literature by performing his own tests to detect degradation is only one facet of his testimony. I will not order a blanket exclusion of Dr. Iakovlev's degradation testimony based on Ethicon's misleading representations.

I will, however, address Ethicon's specific challenge. Ethicon disputes the reliability of Dr. Iakovlev's opinion that he can detect degradation bark because it traps histological dyes. Ethicon claims this opinion rests on an implicit untested hypothesis, which is inconsistent with the scientific method. Ethicon is basically

demanding that Dr. Iakovlev artificially try to replicate degradation with oxidation outside of the body in his lab before he can testify about degradation that allegedly occurred inside the body. The plaintiffs dispute the existence of any untested hypothesis and argue that additional laboratory testing is not necessary to support what Dr. Iakovlev sees from “actual explanted mesh from human beings.” Resp. 8–9 [ECF No. 2185].

While the parties have discussed at length the merits of conducting *in vivo* testing to artificially replicate degradation in a laboratory setting, the court has insufficient evidence to evaluate the methodology Dr. Iakovlev actually employed to examine mesh samples that allegedly degraded *in vivo*. Accordingly, I **RESERVE** ruling until Dr. Iakovlev’s methodology of examining mesh explant samples can be evaluated firsthand at trial.

ii. Linking Degradation to Complications

Ethicon objects to Dr. Iakovlev’s opinions that “degradation needs to be considered as a factor of additional stiffening and late deformations of the mesh” and that “if chemical and physical properties of a material change while it is in the body it should not be used for permanent applications and for anatomical sites from which the devices cannot be safely removed.” Mem. 9–10 [ECF No. 2070] (citing Iakovlev Report 8–9 [ECF No. 2066-4]). Ethicon argues that this is unreliable because Dr. Iakovlev’s writings “tell a far different story.” Mem. 10. I disagree. A review of the citations provided—most of which simply acknowledge the incomplete state of scientific knowledge on this subject and the need for additional study—does not

demonstrate any irreconcilable differences. Even if it did, such contradictions would be better suited for cross-examination than as a basis for exclusion. Accordingly, Ethicon's Motion is **DENIED** on this issue.

iii. Mesh Folding and Deformation

Ethicon also seeks to exclude Dr. Iakovlev's testimony that mesh can fold or curl *in vivo* and that such deformations can cause compartments, which in turn cause pain. Ethicon disputes that Dr. Iakovlev can merely look at a pathology slide and infer that mesh curled or deformed in the body. In response, the plaintiffs do not address the reliability of Dr. Iakovlev's method for determining whether mesh was folded *in vivo*. Accordingly, Dr. Iakovlev's opinions on folding and curling are **EXCLUDED** to the extent they rely solely on his personal analysis of pathology slides, and Ethicon's Motion is **GRANTED** on this point.

b. Complications

Ethicon argues that Dr. Iakovlev failed to use a control in his examination of explanted mesh, thus he is unable to properly correlate specific complications with the samples examined. Ethicon relies on other expert opinions criticizing Dr. Iakovlev's approach to demonstrate that Dr. Iakovlev's opinions are unreliable. The essence of the argument is that Dr. Iakovlev did not compare examined tissue slides of patients complaining of pain to slides of tissue from patients who did not complain of pain yet nonetheless had their mesh devices removed. The plaintiffs argue that Dr. Iakovlev compared his samples to "normal tissue" present within the same slides. Ethicon argues that "Dr. Iakovlev's comparison of his pathological findings to normal

tissue within the same slide does not constitute a control, since he cannot rule out the fact that patients not suffering from pain may have the same pathological presentation based on this comparison.” Reply 11 [ECF No. 2251]. I agree. Without a proper control, Dr. Iakovlev’s opinions correlating specific complications with samples of explanted mesh products do not provide a sufficiently reliable methodology. *See Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *28 (S.D. W. Va. Sept. 29, 2014) (“Vigorous adherence to protocols and controls are the hallmarks of ‘good science.’” (citing to *Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 603 (S.D. W. Va. 1998))). To the extent that Dr. Iakovlev offers complications opinions based on his examination of explanted mesh samples without the use of a control sample, his complications opinions are **EXCLUDED**.

Ethicon next argues that Dr. Iakovlev ignored relevant scientific literature, specifically, Dr. Hill’s study entitled *Histopathology of Excised Midurethral Sling Mesh*. Dr. Iakovlev’s alleged failure to review a particular study in forming his opinion is better suited for cross-examination, particularly when Dr. Iakovlev has supported his opinions with numerous other studies. Ethicon’s Motion is **DENIED** on this point.

Ethicon next argues that a certain paper that Dr. Iakovlev co-authored reveals that his methodology is not scientifically legitimate. Ethicon points to the following quote from the paper as evidence that Dr. Iakovlev is unable to form opinions regarding complications: “At present, general human tissue interactions with the mesh are known, but we have an incomplete understanding of interactions specific to

a mesh material and design as well as the pathophysiology of any complications.” Mot. re: Dr. Iakovlev, Ex. O at 15 [ECF No. 2066-17]. The standards elucidated in *Daubert* certainly do not require an expert to have a “complete understanding” of an issue in a particular field, and the reality is that a complete understanding of anything in science is virtually unattainable. Dr. Iakovlev has supported his opinions with his own experience and citation to scientific literature. To the extent that Ethicon believes that Dr. Iakovlev has made inconsistent statements regarding his opinions, Ethicon is free to cross-examine him on those points. Ethicon’s Motion on this point is **DENIED**.

Ethicon next challenges Dr. Iakovlev’s qualifications to offer opinions regarding certain alleged complications, such as thromboses, occlusions of capillaries, and arterioles. Additionally, Ethicon challenges Dr. Iakovlev’s opinion that “the presence of smooth muscle in mesh pores reveals that the mesh has migrated because smooth muscle has a restricted ability to regenerate.” Mem. Supp. Mot. re: Dr. Iakovlev 16 [ECF No. 2070]. The basis of Ethicon’s arguments is centered on Ethicon’s own experts’ criticisms of Dr. Iakovlev’s conclusions. The simple fact that Ethicon’s experts disagree with Dr. Iakovlev does not mean Dr. Iakovlev is rendered unqualified under *Daubert*. Dr. Iakovlev is a highly experienced clinical pathologist, and he is qualified to render his complications opinions based on his knowledge, skill, education, and experience. Ethicon’s Motion on this point is **DENIED**.

Next, Ethicon argues that Dr. Iakovlev’s opinions regarding the presence and clinical significance of “nerve twigs” or “nerve branches” are inconsistent with the

scientific method and medical facts. Again, the basis for Ethicon’s challenge is that Ethicon’s own experts disagree with the ultimate opinions Dr. Iakovlev offers. Differing opinions reached by opposing experts is not an appropriate challenge under *Daubert*. Dr. Iakovlev has sufficiently explained his opinions regarding nerve branch entrapment and distortion, and such opinions are within his specialty as a clinical pathologist. Ethicon’s Motion on this point is **DENIED**.

Ethicon next challenges as unreliable Dr. Iakovlev’s opinion that the presence of an erosion necessarily implies that a patient has a wound infection. Ethicon points to deposition testimony where Dr. Iakovlev testified that “erosion is always associated with localized infection.” Iakovlev Dep. 14:2–6, March 13, 2016 [ECF No. 2066-29]. Dr. Iakovlev does not provide any support for his opinion that erosion is *always* associated with localized infection other than stating his own experience. Even his report, which states that “[m]ucosal erosion of the transvaginal Ethicon mesh becomes a chronic open wound and an entry for infectious organisms,” provides no citation to scientific literature. Report 18 [ECF No. 2066-4]. Dr. Iakovlev’s opinion, which would universally apply to all Ethicon mesh, is simply not supported with cited scientific literature. Dr. Iakovlev’s opinions on this point are unreliable, and they are **EXCLUDED**.

c. Mesh Explants

Ethicon argues that Dr. Iakovlev should not be permitted to testify on the basis of mesh explants that are not the subject of this litigation because he “previously testified that he could not determine the origins of many of the slides used in his

reports.” Mem. 22. Such indeterminacy raises concerns about the integrity of Dr. Iakovlev’s data pool, as the selection and origin of samples may necessarily affect the conclusions that may reliably be drawn from them. To the extent that Dr. Iakovlev cannot determine the origin of the slides on which his opinions are based, such opinions are **EXCLUDED** as unreliable.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in part** as described below.

I have repeatedly excluded evidence regarding the FDA’s section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 (“[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value.”).

Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors “to erroneously conclude that regulatory compliance proved safety.” *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon’s compliance with or violation of the FDA’s labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon’s compliance with design control and risk management standards. Some of this testimony involves the FDA’s quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product’s risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the

device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion. Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from

using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) (“[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.”); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (“Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.”). Additionally, an expert may not offer expert testimony using “legal terms of art,” such as “defective,” “unreasonably dangerous,” or “proximate cause.” *See Perez v. Townsend Eng’g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of

Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

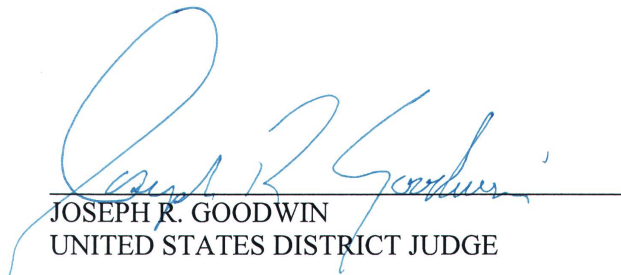
Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be exclude, the parties ask the court to prevent experts from offering other expert testimony that the moving party claims the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part, GRANTS in part, and RESERVES in part** the Motion to Exclude the Opinions and Testimony of Dr. Vladimir Iakovlev [ECF No. 2066].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: September 1, 2016


JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE